

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

**IN RE: ETHICON, INC. PELVIC REPAIR
SYSTEM PRODUCTS LIABILITY
LITIGATION**

THIS DOCUMENT RELATES ONLY TO:

ETHICON WAVE 2 & 3 CASES

**Master File No. 2:12-MD-02327
MDL No. 2327**

**JOSEPH R. GOODWIN
U.S. DISTRICT JUDGE**

**DEFENDANTS' MOTION FOR A PROTECTIVE ORDER RELIEVING
DEFENDANTS OF RESPONDING TO PROVISION IN DEFENDANT'S FACT SHEET
REQUIRING PRODUCTION OF DEVICE HISTORY RECORDS**

Defendants respectfully move the Court to enter a protective order relieving them of responding to one provision concerning device history records in the Defendant's Fact Sheet ("DFS") in connection with Wave 2 cases and any subsequent waves of cases.

When Defendants originally negotiated the content of the DFS, it was with the understanding that a DFS would only be required for *twenty* plaintiffs at a time according to the Court's pretrial orders. Since then, however, the Court has instructed the parties to prepare the oldest *200 cases* for trial as a first "wave" – and recently entered an order selecting the cases for a second wave of equal size. Defendants prepared a DFS for each Plaintiff in Wave 1 and, in doing so, have come to appreciate the extraordinary burden involved in responding to the DFS's request for production of each plaintiff's device history records. As the attached declaration attests, compiling the device history records for each Plaintiff in Wave 1 has cost Ethicon approximately 2,700 hours of employee work time. On the other hand, Plaintiffs in this MDL have yet to even use such Plaintiff-specific discovery at *any trial or deposition* in connection with an individual Plaintiff's case. In light of the federal rules' insistence that discovery's

burden be proportional to its benefit, this particular request is simply too burdensome without first requiring some particular showing of need.

For these reasons, Defendants respectfully request that the Court enter an order relieving them of producing Plaintiffs' device history records for Wave 2 and any subsequent wave(s) unless a particular plaintiff demonstrates a specific need for it.

BACKGROUND

Early in the MDL process, the Court issued a number of discovery orders intended to address the administrative and economic realities of multidistrict litigation, including pretrial order ("PTO") # 17, which was entered by the Court on October 4, 2012. *See PTO # 17, In re Ethicon, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-md-2327 (S.D. W. Va. Oct. 4, 2012), available at <http://www.wvsd.uscourts.gov/MDL/ethicon/orders.html>. Pursuant to PTO # 17, Defendants agreed to complete a DFS "only in those cases selected as a subgroup (*not to exceed 20 cases*) from which the final bellwether selection will be made." PTO # 17 at 6 (emphasis added). On August 19, 2015, however, the Court directed the parties to develop for trial the **200 oldest cases** in the Ethicon MDL proceeding. *See PTO # 193, In re Ethicon, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-md-2327 (S.D. W. Va. Aug. 19, 2015), available at <http://www.wvsd.uscourts.gov/MDL/ethicon/orders.html>. Since then, the Court has ordered the parties to work up a second wave of 200 cases, and suggested that additional waves may follow. *See PTO # 206, In re Ethicon, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-md-2327 (S.D. W. Va. Nov. 20, 2015), available at <http://www.wvsd.uscourts.gov/MDL/ethicon/orders.html>. (*See also* e-mail from K. Fife to T. Cartmell, R. Baggett, C. Jones, D. Jacobs, D. Wigley, and B. Thomas, "Ethicon Wave 2," Oct. 8, 2015 (attached as Ex. 1).)

The DFS solicits responses to dozens of requests and production of five categories of documents for each individual Plaintiff. *See* Defendant's Fact Sheet at 1-4 (attached to PTO # 41). Just one of those requests is at issue here. Specifically, the DFS requires Defendants to “[p]roduce a true and complete copy of the device history record for [each] Plaintiff’s lot and reference number(s).” *Id.* at 4.¹ A device history record is a collection of manufacturing records pertaining to a lot of finished goods that includes documentation related to packaging, component and raw material lot records, and sterilization records. (*See* Declaration of Carmel Lowe, Nov. 24, 2015, ¶ 5 (attached as Ex. 2).)

Approximately **2,700 hours** of employee time will have been devoted to compiling the device history records for just the Wave 1 cases, according to Ms. Carmel Lowe, Ethicon’s Quality Systems Supervisor in Neuchatel, Switzerland. (*Id.* ¶ 16.) As she describes in her declaration, Ethicon Sarl maintains hard copies of the manufacturing records for each of the raw materials and components that make up the TVT family of products. (*Id.* ¶ 8.) In order to compile a device history record, an Ethicon employee must identify the lot number and review the relevant Lot Travel Record, which in turn identifies the raw material lots, component part lots, and additional sterilization information. (*Id.* ¶ 9.) The employee then has to find the documentation associated with each of the identified component lots using the Company’s record retention schedule. (*Id.* ¶ 10.) This often involves coordinating retrieval of the documentation offsite at the Secur Archive facility in Bern, Switzerland, where documentation for products manufactured two or more years ago is stored. (*Id.*) Once the employee compiles the documentation for each lot, a Quality Assurance technician, as well as Ms. Lowe herself, reviews

¹ In particular, Defendants seek relief from request V.C. of the DFS.

for accuracy and completeness before the documents are distributed outside the Company. (*Id.* ¶¶ 12-13.)

Though the volume of each device history record varies depending on the number of unique raw materials and components used in the manufacture of a finished lot, the average record consists of 40-50 pages. Some can be “upwards of 100 pages.” (*Id.* ¶ 14.) Despite the relatively small number of pages, collection is extremely time consuming because the documentation must be compiled manually by trained employees. (*Id.*) Therefore, Ethicon is capable of compiling only 5-7 device history records per week, on average. (*Id.*)

Generally, Ethicon is not able to absorb such a high level of litigation-related activity. (*Id.* ¶ 17.) For the Wave 1 cases, another Johnson & Johnson franchise lent Ethicon four of its employees to assist the three full-time employees Ethicon itself had devoted to the project. (*Id.*) Ms. Lowe makes clear in her declaration, however, that if similar productions are required for Wave 2 and any additional waves, she would need to hire and train additional employees. (*Id.*)

Defendants have met and conferred with Plaintiffs on these issues in connection with the Wave 1 cases, but could not reach agreement.

ARGUMENT

As the U.S. Court of Appeals for the Fourth Circuit has made clear, “the simple fact that requested information is discoverable under Rule 26(a) does not mean that discovery must be had.” *Nicholas v. Wyndham Int'l, Inc.*, 373 F.3d 537, 543 (4th Cir. 2004). “On its own initiative . . . a district court may limit ‘the frequency or extent of use of the discovery methods otherwise permitted’ under the Federal Rules of Civil Procedure if it concludes that . . . ‘the burden or expense of the proposed discovery outweighs its likely benefit.’” *Id.* (quoting Fed. R. Civ. P. 26(b)(2)). Further, in response to a motion for protective order under Rule 26(c), the

court may, for good cause, protect a party from discovery that would cause “undue burden or expense.” Fed. R. Civ. P. 26(c)(1); *see also* 8A Charles Alan Wright et al., *Federal Practice and Procedure* § 2036 (3d ed. Westlaw 2015) (“Rule 26(c) was adopted as a safeguard for the protection of parties and witnesses in view of the almost unlimited right of discovery.”). In other words, in determining whether to restrict discovery, “the Court must weigh the need for the information versus the harm in producing it.” *A Helping Hand, LLC v. Baltimore Cty.*, 295 F. Supp. 2d 585, 592 (D. Md. 2003) (citation omitted); *see also* Wright, *supra* § 2036 (“discovery has limits and . . . these limits grow more formidable as the showing of need decreases”). Where a party goes beyond “stereotyped and conclusory” allegations of harm, and offers a “particular and specific demonstration” of undue burden, the court should exercise its “broad discretion” to restrict discovery. *Wymes v. Lustbader*, No. WDQ-10-1629, 2012 U.S. Dist. LEXIS 68490, at *13-14 (D. Md. May 16, 2012).

Defendants have made such a showing here. The discovery sought by this DFS provision creates a disproportional burden that should not be allowed without some showing of specific need in a particular case. When the parties originally negotiated the substance of the DFS, it was under the premise that the DFS would be required for groups “***not to exceed 20 cases***” at a time – not multiple rounds of 200. PTO # 17 at 6 (emphasis added). Nevertheless, Defendants moved forward with completing a DFS for each of the 200 Plaintiffs in Wave 1. That experience made clear to Defendants how burdensome producing the device history records would be – and allowed for the concrete explanation in the attached declaration of the time-consuming process the discovery actually requires.

Because each Plaintiff is implanted with a different device, it is highly unlikely that any of the materials Defendants produced for the Plaintiffs in Wave 1 can be reused. Indeed, the

discovery produced for Wave 1 demonstrated that there was little to no overlap of lot numbers associated with Plaintiffs' devices. (See Lowe Decl. ¶ 15 (stating that there were greater than 200 *unique* lots identified for the 200 cases in Wave 1).) Thus, Defendants will be forced to go through the same time-consuming efforts described above for each additional wave of plaintiffs. As Ms. Lowe attested, it will take Ethicon employees **2,700 hours** to manually collect the device history records for 200 plaintiffs. (*Id.* ¶¶ 14, 16.) This is, of course, in addition to the **thousands** of hours counsel has and will spend preparing DFS's for Plaintiffs, separate and aside from the burdens of the specific request at issue.

Such oppressive, burdensome discovery is completely disproportionate to Plaintiffs' need for the information. In fact, Defendants are ***not aware of any instance where a plaintiff in this MDL has actually used such discovery*** either at trial or in a deposition in connection with her individual case. This is unsurprising given the lack of relevance of this information to the issues at hand. Defendants assume Plaintiffs request the device history records to determine whether any particular device suffers from a manufacturing defect. However, these records would not provide evidence to that effect. (*See id.* ¶ 6.) While any non-conformance reports associated with a particular batch would be referenced in the device history record, a lot is not released until any associated non-conformances are resolved, which would be documented as well. (*See id.* ¶ 5-6 (explaining that the records document each step in the manufacturing process and that proper steps, including cleaning and sterilization, are taken).) Moreover, Defendants have already produced summary non-conformance reports, which can be identified in the production by lot number.

Under such circumstances, it would be entirely unfair to blindly require Defendants to undertake this taxing process for all 200 cases in Wave 2 (not to mention the hundreds more that

may be forthcoming in subsequent waves) merely because the DFS – which was negotiated under different parameters – calls for it. Instead, the Court should relieve Defendants of producing such information *until* some specific showing of need is made by a particular plaintiff who can show that such discovery is necessary to her case. *See Manual for Complex Litigation (Fourth)* §§ 11.31, 11.42 (2004) (initial discovery will often “provide information for further defining and narrowing issues, which may lead to revision and refinement of the discovery plan”; an MDL judge should “monitor the progress” of discovery, “ensur[ing] that it is operating fairly and effectively, and adjust it as needed”).

For all of these reasons, the Court should grant Defendants’ motion for a protective order.²

² To the extent the Court allows Plaintiffs to pursue this discovery, it should – at the very least – require them to bear the significant cost of that discovery. As the U.S. Supreme Court has explained, while “the presumption is that the responding party must bear the expense of complying with discovery requests,” it may “invoke the district court’s discretion” to grant orders protecting it from undue burden and expense, “including orders conditioning discovery on the requesting party’s payment of the costs of discovery.” *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 358 (1978); *see Fed. R. Civ. P. 26* advisory committee’s notes (“Rule 26(c)(1)(B) is amended to include an express recognition of protective orders that allocate expenses for disclosure or discovery. Authority to enter such orders is included in the present rule, and courts already exercise this authority. Explicit recognition will forestall the temptation some parties may feel to contest this authority.”). Consistent with this ruling, courts have held that “where the cost of producing documents is very significant, [a district court] has the power to allocate the cost of discovery” to the requesting party. *See, e.g., Boeynaems v. LA Fitness Int’l LLC*, 285 F.R.D. 331, 341 (E.D. Pa. 2012) (ordering plaintiffs to pay cost of additional discovery beyond the hundreds of thousands of documents already produced by the defendant; “given the large amount of information [d]efendant has already provided, [p]laintiffs need to assess the value of additional discovery” and decide whether it is truly worth the cost to them); *Foreclosure Mgmt. Co. v. Asset Mgmt. Holdings, LLC*, No. 07-2388-DJW, 2008 U.S. Dist. LEXIS 72513, at *21-23 (D. Kan. Aug. 13, 2008) (explaining that in order to determine whether cost-shifting is appropriate, the court must assess whether “the burden or expense of the proposed discovery outweighs its likely benefit”; holding “that it would be appropriate to apportion the costs of th[e] discovery equally” between the plaintiff and defendant where the plaintiff estimated it would take 2000 hours to produce the requested documents). The Court should do so here given the disproportional burden placed on Ethicon to produce this information that has yet to demonstrate *any* importance to Plaintiffs’ cases.

CONCLUSION

FOR THESE REASONS, Defendants respectfully request that the Court enter a protective order relieving Defendants of responding to the inquiry on the Defendant's Fact Sheet concerning device history records for the Wave 2 and subsequent waves of cases until a particular plaintiff demonstrates a need for such information.

ETHICON, INC., ETHICON LLC AND
JOHNSON & JOHNSON

/s/ David B. Thomas

David B. Thomas (W. Va. Bar No. 3731)
Thomas Combs & Spann, PLLC
300 Summers Street, Suite 1380
P.O. Box 3824
Charleston, WV 25338-3824
(304) 414-1800

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CERTIFICATE OF SERVICE

I, David B. Thomas, certify that on November 24, 2015, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ David B. Thomas

David B. Thomas (W. Va. Bar No. 3731)
Thomas Combs & Spann, PLLC
300 Summers Street, Suite 1380
P.O. Box 3824
Charleston, WV 25338-3824
(304) 414-1800

COUNSEL FOR DEFENDANTS ETHICON, INC.,
ETHICON LLC, AND JOHNSON & JOHNSON